PSJ3

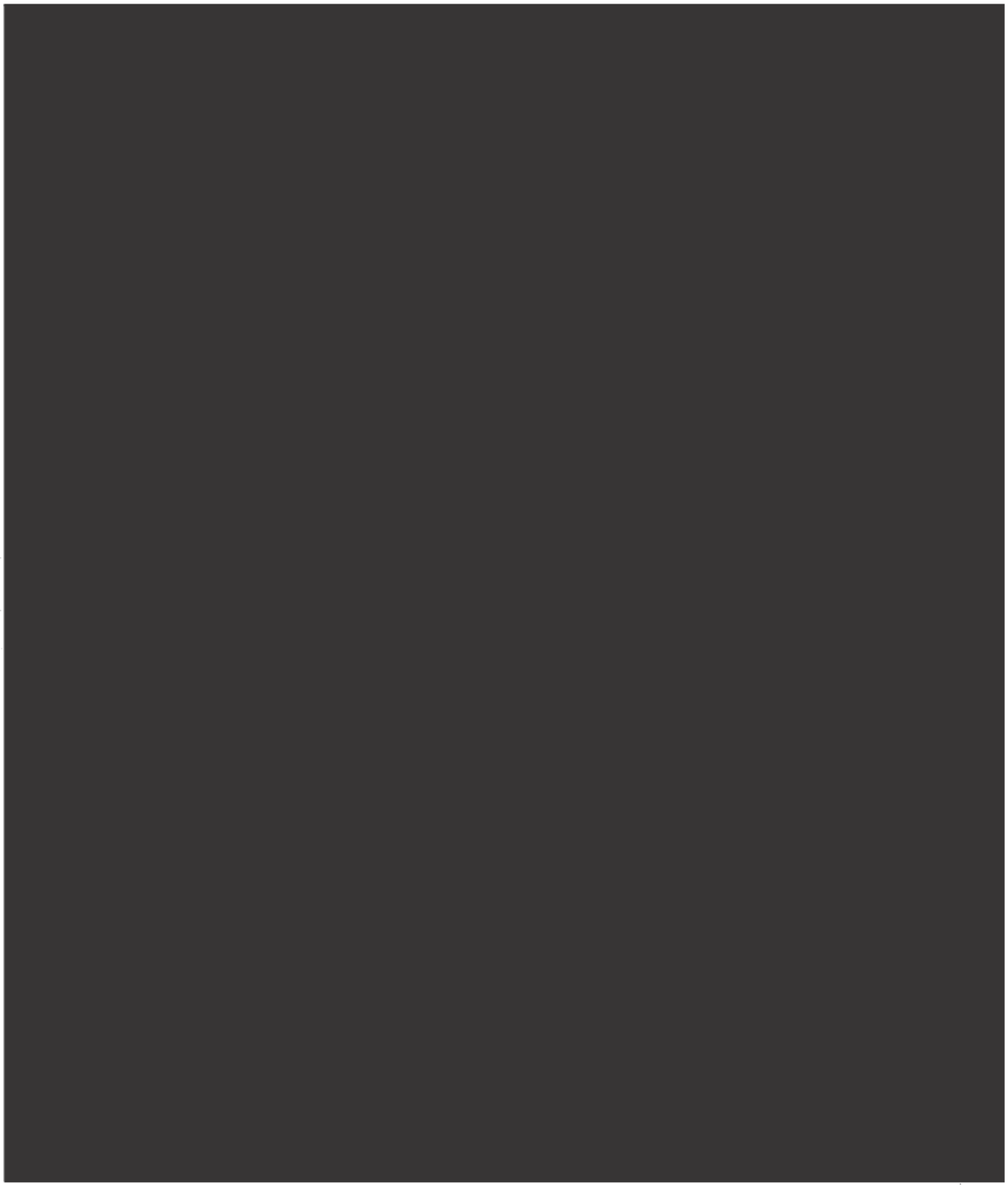
Exhibit 393

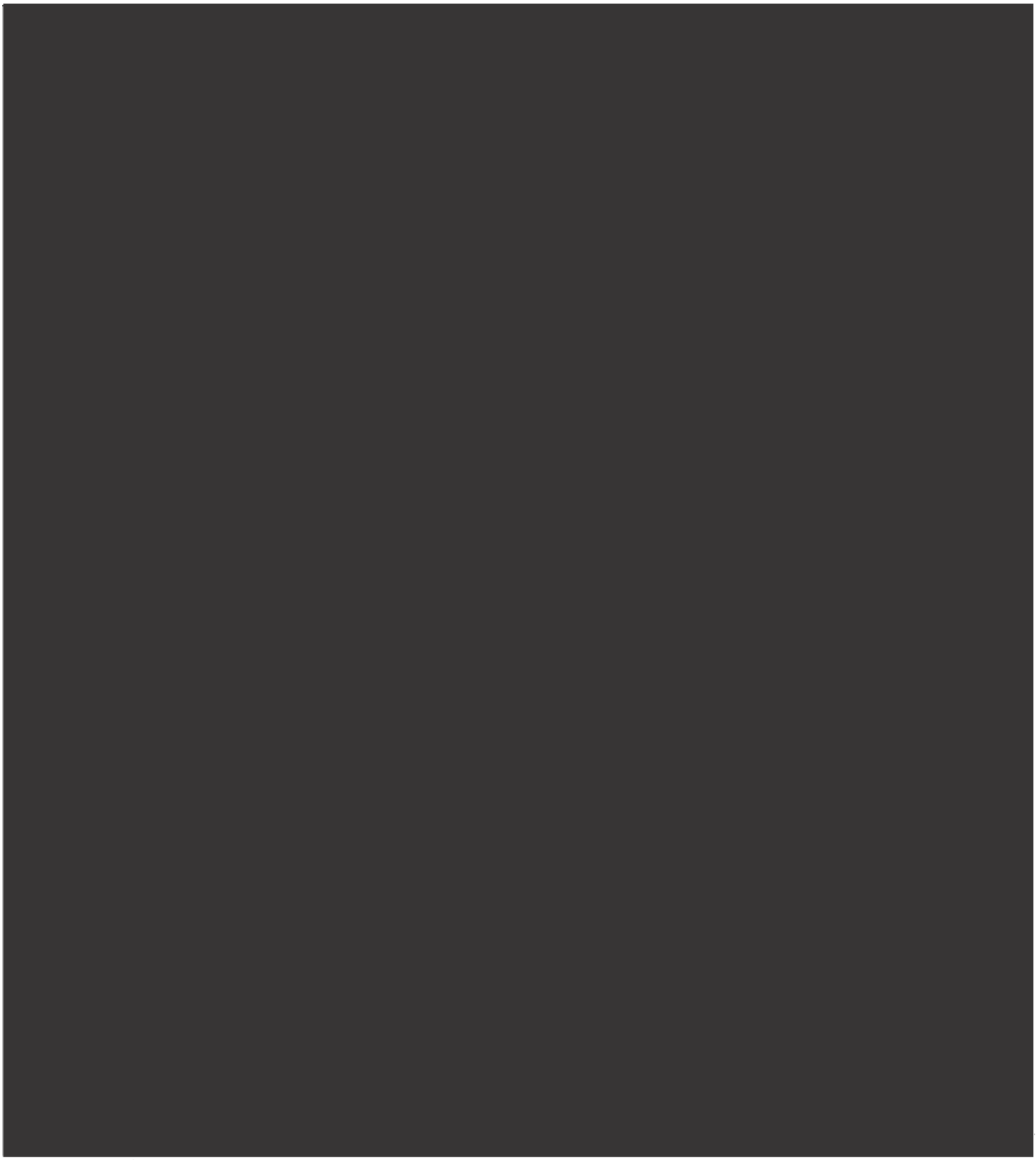
HDMA STAFF PERFORMANCE APPRAISAL FORM 2008

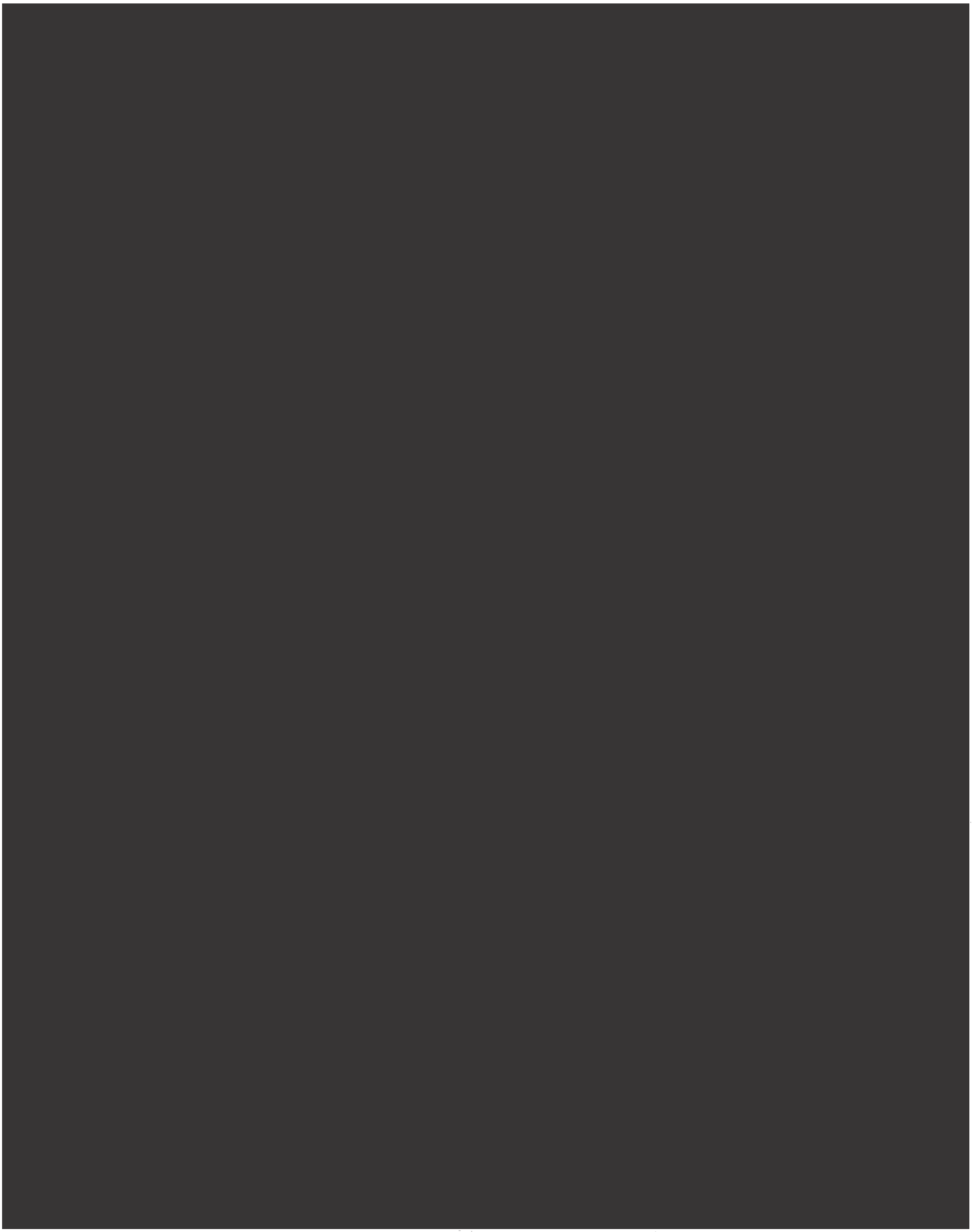
Name:	Anita Ducca
Title:	Senior Director, Regulatory Affairs
Department:	Government Affairs
Period:	**January – December 2008**
Supervisor:	Scott Melville

PERFORMANCE LEVELS

[redacted]







SUPERVISOR COMMENTS – Prepare the following considering the overall year's performance and specifically as it relates to the 2008 goals.

Noteworthy strong areas of present performance:

[redacted]

From an issues perspective, Anita had a particularly strong year. In particular, she managed a growing number of DEA issues requiring the association's attention. She continued her efforts, begun in 2007, to develop a model Industry Compliance Guideline (ICG) for suspicious orders. She led internal drafting efforts, with assistance from the membership and outside consultants, and the document was ratified by the HDMA Board and praised by the DEA General Counsel in a letter to HDMA. The DEA letter was the result of direct negotiations with the Administration, and Anita was a key member of that negotiation team. This was, overall, an outstanding effort for which Anita deserves significant praise. In addition, Anita managed oversight of additional DEA issues, facilitated or participated in additional meetings with DEA and our membership, and included DEA participation in the DMC agenda.

As always, Anita maintained close oversight on all FDA issues, including assisting in the preparation and submission of comments on the FDAAA request for information. Moreover, she played the lead role in facilitating HDMA participation in the Import Safety Summit, a key initiative of Secretary Leavitt and including the involvement of FDA Commissioner, Dr. Von Eschenbach. She has also strategically identified REMS as an emerging FDA issue with significant implications for our membership. She is participating on a REMS task force with the Pain Coalition and producing REMS programming for our upcoming GPPC and DMC meetings.

[redacted]

Areas requiring improvement in job performance:

[redacted]

What has the employee done to improve performance from the previous review:

[redacted]

Developmental Plans/Corrective Actions:

[redacted]

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*Supervisor must submit completed review to the Department Head and Human Resources, prior to the performance discussion with the employee, a detailed plan to address "marginal/needs improvement" performers.

SIGNATURES: Signatures acknowledge that this form was discussed and reviewed.

HR Signature: _____ **Date:** 12-22-09

Next Level Supervisor Signature: _____ **Date:** _____

Direct Supervisor Signature: _____ **Date:** 12-31-09

****

Employee Signature: _____ **Date:** 1/7/09

EMPLOYEE COMMENTS: Submit as attachment with signature and date.

Comments Attached: Yes **(No)**

HDMA EMPLOYEE SELF EVALUATION FORM AND GOALS DOCUMENT UPDATE 2008

Name:	Anita T. Ducca
Title:	Senior Director, Regulatory Affairs
Department:	Government Affairs
Period:	**January – November 2008**
Supervisor:	Scott Melville

1. **SELF EVALUATION:** Please rate yourself based on your job performance for the last period in terms of: (scale of 1 to 9, 1 = low, 9 = high). See HDMA Staff Appraisal Form for definitions.

[redacted]

2. Attach your updated goals document with the status of each goal for 2008.

3. Review your job description and make sure it is accurate for your current responsibilities. Attach a modified copy if necessary.

4. What have you done to add value to the organization? (i.e., improved a process, saved money for the association, etc.) This should be 1-3 examples.

I have significantly improved HDMA's working relationship with the DEA. This was accomplished by establishing a line of communications with key DEA officials for example, by developing and hosting the July 17 DEA-HDMA meeting. This improved relationship has supported HDMA's ability to proactively and positively influence DEA's decisions that significantly impact HDMA members.

I was the lead on the substantive contents and development of the industry Compliance Guidelines (ICG), which stabilized and clarified DEA expectations and requirements for monitoring and reporting of controlled substances suspicious orders. This effort has helped HDMA members avoid significant compliance difficulties including potentially catastrophic suspension of DEA registration. It should also be noted that DEA sent HDMA a letter of commendation for the ICG.

[redacted]

5. What are your goals for 2009 and how will the success or achievement of the goals be measured? This should be 3-5 specific goals, see attached sample.

1. Continue to enhance communications between HDMA and DEA. Focus on aiding DEA's ability to achieve its safety objectives while still allowing viable and efficient distribution practices/systems.

Objective: Establish meeting between HDMA (and its members) and DEA officials to discuss and explain the distribution industry and to better underst and DEA's safety issues. ng for suspicious

2. Support HDMA's educational goals.

Objective: Develop at least two sessions for the DMC, at least one of which discusses DEA issues relevant to HDMA members.

3. Goal: Strive to Develop and execute a strategy to address the industry's concerns with regard to FDA's implementation of FDAAA's REMS requirements.

Objective: Identify opportunities to positively influence FDA's and the drug manufacturers' plans for REMS. (Include DEA and their related initiatives as appropriate.) Participate in the Pain Care Forum's initiative to develop a REMS program that will "educate" prescribers and briefing the

6. What can your supervisor and/or HDMA do to help? (i.e., technical training, more communication, improved feedback, etc.)

[redacted]

7. Additional comments?

[redacted]

Updated 2008 GOALS

EMPLOYEE: **Anita T. Ducca**
POSITION: **Senior Director, Regulatory Affairs & Healthcare Policy**
FOR PERIOD: **January 1, 2008 – December 31, 2008**

JOB ELEMENTS:

1. **Strive to identify opportunities to incorporate of HDMA's position(s) on federal regulatory initiatives affecting the wholesale distribution industry. Work toward creating changes in federal regulatory requirements reflective of HDMA member's policy positions. 45%**

SPECIFIC GOALS

- Work toward identifying critical federal regulatory and related initiatives impacting the distribution industry, analyzing their impact, and toward development of strategies to support HDMA polices.

- DEA - Launch an initiative to proactively define DEA regulatory issues, develop policy positions and advocate such positions on behalf of HDMA's members. Includes, but is not limited to:

    - Suspicious Orders requirements and interpretations of implementing regulations
    - In-Transit Losses
    - Requirements for obtaining regulated sellers' self-certification numbers
    - Methadone
    - Iodine registration requirements

- Risk Management and Related Initiatives – Proactively identify and define FDA Risk Management and related regulatory issues, develop policy positions and advocate such positions on behalf of HDMA's members. Includes, but is not limited to:

    - Risk Management
    - Medication Guides
    - Electronic PIs
    - iPLEDGE

- As needed, strive to conduct appropriate follow-up interactions to further support written comments and oral testimony on the NDC rule particular regarding repackaging and definitions of relabeling.

- PDMA:

- Work with FDA staff to further clarify remaining questions and to seek revisions with respect to FDA's guidances (particularly the Q & A guidance issued in Nov. 2006) that are comparable to HDMA's prioritized positions.
- Strive to develop and advocate regulatory policies and positions designed to implement legislation directing FDA to develop standards for unique identifiers.
- Strive to develop and advocate HDMA policies and positions on FDA efforts to implement anticipated uniform (electronic) pedigree/track and trace legislation.

- Strive to enhance familiarity with, and conduct outreach to, key agency staff and stakeholders. Includes outreach among, senior and political appointee and other regulatory agency staff including staff of the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA). Also includes staff of Trade Associations with interests in common to HDMA and its members (e.g., NACDS, NCPA, CHPA, etc.)

- Participate in additional HDMA committee meetings and seek to develop policies and communications regarding regulatory initiatives that require Government and Public Policy Council (GPPC) and the Government Affairs Committee (GAC) review/acceptance. Includes, but is not limited to, recommending regulatory policies and strategies for Committee consideration.

Accomplishments for #1

Successfully launched and completed a comprehensive initiative to develop "Industry Compliance Guidelines" for reporting suspicious orders. Efforts included:

- **Retained and managed a consultant and oversaw development of the ICG. Ensured committee reviews and follow-up revisions (RAC & GPPC) including a large face to face review meeting with HDMA RAC members.**
- **Discussed ICG with external stakeholders, including the DC-based Pain Care Forum on 1/11; and NACDS/NCPA/APhA Jan. 24 and Nov. 3.**
- **Worked with Outside Counsel and others to strategize DEA interactions, review, and final acceptance of the ICGs (3 DEA meetings total.)**
- **HDMA received a DEA letter of commendation on the ICG (October).**
- **Developed and provided a Webinar for HDMA members.**
- **Am currently planning follow-up including a DMC session.**

Additional DEA efforts:

- **Held a very successful meeting with Mark Caverly and additional DEA officials on July 17th. Discussed many DEA issues and HDMA members were very pleased with the meeting.**
- **Am currently preparing for a follow-up DEA meeting that we hope will take place early next year. Will stress "educating" DEA.**
- **I requested that DEA provide an update of the list of facilities eligible to receive Methadone 40 mg tablets under the Advisory. Received the list from DEA and arranged for communication to our members.**

- Presented HDMA's views on Controlled Substances before the APhA at the APhA Board of Trustees and Affiliated State Pharmacy Association Executives (ASPAE) Meeting (September 14).
- Oversaw the Manager of Regulatory Affairs efforts to
  - prepare comments on the DEA Form 222 proposed regulation, (We've heard that DEA is likely to back off of this proposal.)
  - summarize current security practices to prevent in-transit losses, and
  - prepare and communicate policy positions for the in-transit losses meeting at NABP.

- Identified the need for taking action on the final Iodine rule (which requires dual Controlled Substances and List I Chemical handler registration of distributors) and oversaw development of a "petition" requesting that DEA reopen the rulemaking comment period.

FDA and Other Issues:

Identified the need for responding to FDA's request for comments on implementing FDAAA's Risk Evaluation and Mitigation Strategies (REMS); managed OFW in preparation of comments; developed certain key policy elements for the comments. (Two sets of comments on REMS were prepared, one in the FDAAA 5-year plan which mentions REMS and the other in response to the Federal Register request for manufacturers to submit their REMS to FDA.)

Participated in the response preparation for FDA's request for comments on implementation of Technologies and Standards provisions in FDAAA (Section 913). Identified key policy approaches to address concerns with "validation" provisions.

Engaged in a conversation with FDA to find out what their plans are for the final NDC rule.

Oversaw the Manager of Regulatory Affairs review of the Single Patient Document Petition (i.e., the NACDS petition prepared by OFW to create an alternative to MedGuides) and submission of comments prepared by OFW on Paperwork Reduction Act elements of MedGuides.

Oversaw HDMA's participation in an HHS Import Safety Summit.
- Met with and developed relationships with representatives of allied trade associations (Bio, PhRMA, CHPA, GPHA) to discuss Medical Panel presentations, and with HHS representatives to plan the Summit (numerous meetings were held).
- Managed budget request for sponsorship.
- Reviewed and developed policies on HHS materials.
- Developed first draft talking points and Qs and As.
- Coordinated with appropriate HDMA and HHS staff.

Analyzed the WHO/IMPACT final draft Good Distribution Practices (GDP) Guidance. Identified numerous problem areas and notified the IFPW and FDA of appropriate corrections. (September 2008)

Submitted HDMA comments in response to FDA's request for information on the impact on availability of Dextromortphan (DEX) should FDA/DEA decide to schedule it as a controlled substance. (October 2008)

2. **Lead HDMA Regulatory Affairs Committee (RAC) and Regulatory Affairs and Healthcare Policy budget process activities, and participate in HDMA educational programs and HDMA committee management. 20%**

SPECIFIC GOALS

- Act as staff to the RAC. Strive to establish appropriate agenda, identify priorities for RAC consideration, and work with the committee to develop policies consistent with industry goals.
- Strive to identify at least one educational session for the Distribution Management Conference, solicit a speaker and work with the speaker to develop the session.
- Work towards establishing a federal Regulatory Affairs budget that adequately funds agreed-to priorities.
- Strive to administer of the Regulatory Affairs budget without exceeding budget allocations.

Accomplishments for #2

Coordinate two conference calls per month (develop agenda, identify issues, positions, etc.) and more as needed.

Develop policy positions on rulemakings and similar government initiatives (See specific issues identified under #1 above)

Track and communicate to membership developments in the RxUSA v. FDA lawsuit.

Involve Mark Caverly in DMC (Mark spoke on "A View from the DEA: Trends, Regulations & Interpretations"); similarly developed concept for David Durkin's presentation at DMC; and presented the Regulatory Affairs portion of the Pedigree Update panel at DMC.

Review/update financials monthly; currently developing 2009 budget.

3. **Work towards enhancing the Policy Development Program. 10%**

SPECIFIC GOALS

- Work towards identification of issues critical to HDMA membership suitable for in-depth evaluation and analyses.

- Upon identification and agreement with GA Senior V.P., work towards identification of analytical mechanisms and/or expertise to address these issues within allocated budget. Determine suitable end products for use by HDMA and its members. Manage the analysis of identified issues and appropriate communication of final products.

- As priorities permit, act as principal liaison to the HDMA Healthcare Foundation on behalf of Government Affairs. Share information about upcoming GA activities as well as laws impacting HDMA members. Strive to collaborate with Foundation staff on economic or other industry analyses as appropriate.

Accomplishments for #3

Work on Policy Development has not been active primarily due to (1) higher priority issues particularly regarding DEA and (2) reduction in available budget for such activities.

4. Supervise Manager, Regulatory Affairs including efforts to advance and support the HDMA/Regulatory Affairs objectives. 25%

SPECIFIC GOALS

- Provide oversight and guidance on designing strategies to ensure effectiveness of HDMA's advocacy efforts and on appropriate internal and external HDMA teamwork to address these issues.

- Provide guidance on updating and implementing the HDMA AMP Action Plan to address proposed and final AMP rule and on further developing the RSP (or other) alternative(s).

- Provide guidance on monitoring CMS regulatory initiatives, such as the Medicare Part B (ASP) activities and taking appropriate action if needed.

- Provide guidance on monitoring federal regulatory agency efforts to ensure distributor role in pandemic response efforts.

- Strive to continue development of the skills and performance of the Manager, Regulatory Affairs. Includes expanding the Manager's knowledge and responsibilities regarding federal regulatory initiatives beyond CMS to include FDA and DEA.

Accomplishments for #4

Oversaw the Manager of Regulatory Affairs' work efforts including outreach to other trade associations, appropriate identification and follow-up of issues, communication with HDMA members, policy development, budget preparation and financials assessments, and GPPC and Board preparations. Has included the Manager's development of comments and/or positions on:

- The DEA Form 222 proposed regulation,
- US Sentencing Commission's proposed amendments
- Interim final Medicaid rule "Multiple Source Drug Definition" (related to availability of the drug in the states for calculating AMP)
- Comments on the HHS Guidance on Pandemic Influenza Employer Antiviral Stockpiling
- The In-Transit Losses meeting at NABP

Identified issues, such as the proposed Physician Fee Schedule Rule containing ASP elements, and advised Manager, Reg. Affairs on conducting closer scrutiny to determine potential HDMA member impact.

For approximately 3 months, participated in "Coaching" sessions to enhance management and interactive skills. On a continuing basis have acted on suggestions designed to increase and enhance communications and to foster the relationship with the Manager, Reg. Affairs.

Working with the Coach, developed the "Performance Metrics" for Manager to identify performance duties and measures of success for the Manager to achieve during his probationary period.

Separately, developed a Performance Metric Chart as a tool to communicate with the Manager the critical job skills and performance characteristics needed to demonstrate that he was meeting HDMA's expectations at three levels of performance: "Minimum Requirements," "Satisfactory Plus," or "Associate Director" (i.e., promotable performance). HDMA's HR Director indicated she intended to use this chart as a template for defining performance and promotion expectations for other positions within HDMA.

Conducted Manger's Mid-year review. Included review of his updated Goals. I also revised his Job Description to clarify responsibilities. Comprehensively documented discussions, guidance provided, and the Manager's performance.

SUMMARY OF GOALS/WEIGHTS

Strive to identify opportunities to incorporate of HDMA's position(s) on federal regulatory initiatives affecting the wholesale distribution industry. Work toward creating changes in federal regulatory requirements reflective of HDMA member's policy positions. 45%

Lead HDMA Regulatory Affairs Committee (RAC) and Regulatory Affairs and Healthcare Policy budget process activities, and participate in HDMA educational programs and HDMA committee management. 20%

Work towards enhancing the Policy Development Program. 10%

Supervise Manager, Regulatory Affairs including efforts to advance and support the HDMA/Regulatory Affairs objectives. 25%

HDMA EMPLOYEE SALARY ADJUSTMENT FORM

NAME:	Anita Ducca
TITLE:	Senior Director, Regulatory Affairs
DATE OF HIRE:	12/16/2002
SUPERVISOR:	Scott Melville Senior Vice President, Government Affairs
CURRENT SALARY:	[redacted]
APPROVED INCREASE:	[redacted]
NEW SALARY:	[redacted]
EFFECTIVE DATE:	01/01/09
NEXT REVIEW DATE:	01/01/10

Reviewed By H.R. : [signature] Date: 1-5-09

Approved By (Supervisor) : Scott Melville Date: 1-5-09

Employee Signature : Anita T. Ducca Date: 1/7/09

FOR INTERAL USE/PAYROLL/HR ONLY:

1/12/09 Date of processing

[signature] Processed by

HDMA EMPLOYEE SALARY ADJUSTMENT FORM
BONUS

NAME:	Anita Ducca
TITLE:	Senior Director, Regulatory Affairs
DATE OF HIRE:	12/16/2002
SUPERVISOR:	Scott Melville Senior Vice President, Government Affairs
BONUS:	[redacted]
EFFECTIVE:	1/15/2009

[redacted]

Approved By President & CEO : _____ Date: 1/6/09

Employee Signature : Anita T. Ducca Date: 1/7/09

FOR INTERAL USE/PAYROLL/HR ONLY:

1/12/09 Date of processing
_____ Processed by

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CONFIDENTIAL MEMORANDUM

TO: Ann Bittman and Linda Caporaletti-Hoyt

FROM: Scott Melville

DT: 12/19/08

RE: [redacted]

[redacted]

Anita continues to manage a wide-ranging portfolio of regulatory issues and is a highly reliable, productive, and conscientious employee. An area of particularly strong performance has been her stewardship of DEA issues. She established a good working relationship with DEA officials, secured their participation at HDMA meetings, and led the successful effort to develop and negotiate DEA recognition of HDMA's Industry Compliance Guidelines for Suspicious Orders. This was a great effort and a great result which deserves special recognition.

[redacted]